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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,236	08/29/2000	Jiangchun Xu	210121.427C18	9536

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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	16

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/651,236	Xu et al.
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 23, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *64-72* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *64-72* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Sep 23, 2002* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *13*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Currently, claims 64-72 are pending in the instant application. Claims 1-63 have been canceled. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are newly applied as the cancellation of claims 1-63 has rendered all previous rejections, moot. Any rejection not reiterated is hereby withdrawn. New grounds of rejection have been necessitated by amendment. The rejections set forth below constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. It is noted that claim 67 recites a "polynucleotide comprising a sequence having at least 75% identity to the entirety of SEQ ID NO 108", however, SEQ ID NO 108 is a polypeptide. It is assumed that since the preamble recites a polynucleotide, the recitation of SEQ ID NO 108 is in error, and that the claim intended SEQ ID NO 107. Therefore, the claim will be examined as though it recites SEQ ID NO 107. If, however, applicants intended a claim reciting a "polypeptide", such a claim would be withdrawn from consideration as being drawn to non-elected subject matter (see restriction requirement mailed 12/19/2001).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

4. The corrected or substitute drawings were received on September 23, 2002. These drawings are approved.

Claim Rejections - 35 USC § 112

5. Claims 65-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising SEQ ID NO 107 and a polynucleotide comprising the complete complement of SEQ ID NO 107, does not reasonably provide enablement for polynucleotides comprising fragments comprising at least 75 or 150 consecutive nucleotides of SEQ ID NO 107, polynucleotides comprising a sequence having at least 75%, 85% or 95% sequence identity to the entirety of SEQ ID NO 107, polynucleotides having at least 90% or 95% identity to a sequence comprising at least 150 consecutive nucleotides of SEQ ID NO 107, or complete complements of such sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to 1) polynucleotides comprising fragments comprising at least 75 or 150 consecutive nucleotides of SEQ ID NO 107 (claims 65-66), 2) polynucleotides comprising a sequence having at least 75%, 85% or 95% sequence identity to the entirety of SEQ ID NO 107 (claims 67-69), 3) polynucleotides having at least 90% or 95% identity to a sequence comprising at least 150 consecutive nucleotides of SEQ ID NO 107 (claims 70-71), and 4)

complete complements of such sequences (claim 72). Such recitations, encompass mutants, variants and homologs of the polynucleotide of SEQ ID NO 107 as well as fragments which include non coding sequences of the polynucleotide of SEQ ID NO 107, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 is a full length cDNA which was found to be over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 131, line 16-page 132 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out of 5 prostate carcinoma samples tested. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. The claims, however, encompass mutants, variants, and homologs of SEQ ID NO 107, but the specification has not taught any mutants, variants, or homologs of SEQ ID NO 107 that are overexpressed in prostate cancer such that a predictable correlation could be made that mutants, variants, or homologs of SEQ ID NO 107 are overexpressed in prostate tumor tissue. Further, the specification, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that polynucleotides of the invention may comprise a native sequence (sentence bridging pages 33 and 34) or may comprise a variant, or a biological or antigenic functional equivalent of such. The specification,

however, does not teach or describe any variants with mutant or retained biological activity of the polypeptide of SEQ ID NO 108, nor does the specification teach or describe what regions of SEQ ID NO 108 are antigenic, or immunogenic, or responsible for it's biological activity. Although the specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), the specification does not teach the function of any of these splice variants or whether they were over expressed in prostate tumor samples vs normal prostate tissue.

Polynucleotides encompassed by the claims however, include a large number of mutants, variants, and homologs of SEQ ID NOS 107 resulting from missense, frameshift and truncation mutations, from any source, which have not been taught in either the specification or the art. Polynucleotide sequences comprising a fragment comprising at least 75 or 150 consecutive nucleotides of SEQ ID NO 107 or complete complements of such, encompasses fragments that include intronic or non coding sequences of SEQ ID NO 107, that have not been taught in the specification, as well as homologs, mutants, or variants of SEQ ID NO 107 that have only 75 or 150 nucleotides in common with SEQ ID NO 107. Polynucleotides comprising a sequence having at least 75%, 85%, or 95% to the entirety of SEQ ID NO 107, complete complements of such, polynucleotides having at least 90% or 95% to a sequence comprising at least 150 consecutive nucleotides of SEQ ID NO 107 or complete complements of such also encompass mutants, variants, and homologs of SEQ ID 107, from any source, with either retained or altered biological activity, that have not been taught in the specification. However, the specification does not teach the function or biological activity of the polypeptide of SEQ ID NO 108, nor an

assay to measure such, so that the skilled artisan would not know which modifications to the polypeptide of SEQ ID NO 108 would result in a polypeptide with altered biological activity. Further, the specification does not indicate which amino acids of SEQ ID NO 108 are responsible for it's activity such that the skilled artisan might be able to establish a predictable correlation between which amino acids could be altered to provide a polypeptide with either retained or altered biological activity to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity. Therefore, the skilled artisan would first be required to determine the biological activity of the polypeptide encoded by SEQ ID NO 107. Secondly, the skilled artisan would have to determine which amino acids were involved in such function, using trial and error analysis. Such analysis could involve mutating amino acids individually, to determine whether conservative or nonconservative mutations would affect the function of the resulting polypeptide. Given the lack of guidance in the specification as to the function of SEQ ID NO 108, such analysis would be unpredictable, and therefore, constitutes undue experimentation.

A sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal α-methylacyl-CoA racemace which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while the specification,

does not teach or suggest the use of the claimed polypeptides with adult onset sensory motor neuropathy, does not teach the function or biological activity of the polypeptide of SEQ ID NO 108 and specifically teaches that no significant homologies were found with SEQ ID NO 107 and the EMBL and GenBank databases (p. 120, lines 15-16). Therefore, based on the lack of guidance from the specification or the art, the skilled artisan would not be able to determine a predicable correlation between variants, mutants, or homologs of the polypeptide of SEQ ID NO 108 and an association to prostate cancer.

A correlation between mutants, variant and homologs encompassed by the claims and a specific biological activity and it's association to prostate cancer is clearly unpredictable in light of the lack of guidance from the specification and the state of the art with regard to the specific biological function of the polypeptide encoded by SEQ ID NO:108. Since the specification does not teach the specific biological function or activity of the polypeptide of SEQ ID NO 108, and neither the specification nor the art teach how the function of the polypeptide is associated to prostate cancer nor how the skilled artisan could modify the polypeptide of SEQ ID NO 108 to obtain a polypeptide with either modified biological function or retained biological or antigenic activity in association with it's differential expression in prostate cancer, the skilled artisan would be required to perform undue experimentation to make or use the biologically active or altered polypeptides encompassed by the broadly claimed invention. To practice the invention as broadly as it is claimed, the skilled artisan would first have to determine the function of the polypeptide of SEQ ID NO 108 and it's association to prostate cancer. The skilled artisan would

then have to determine what amino acid residues were associated with the expression of the polypeptide in relation to prostate cancer, and then would have to determine which amino acids could be modified to retain biological function, retain the ability to react with antigen specific antisera, or to result in a protein with altered function. Given that the art teaches that a single amino acid change can alter the function of a biomolecule (see Proudfoot et al, Journal of Biological Chemistry, vol. 271, pp 2599-2603, which teaches that extension of recombinant human RANTES by a single residue [Met-RANTES] at the amino terminus was sufficient to produce a potent and selective antagonist - see abstract) and that some of these changes are unpredictable, and given that the specification does not teach the function of the polypeptide of SEQ ID NO 108 and it's association to prostate cancer such analyses would require trial and error, thus constituting undue experimentation. It is noted that because the skilled artisan would be required to perform undue experimentation to make and use the polynucleotides of claims 4-8, and 58, undue experimentation would also be required to make or use vectors and host cells comprising the polynucleotides of claims 4-8 or a kit comprising the oligonucleotide of claim 58.

Response to Arguments

The response traverses the rejection. The response traverses that to practice the claimed invention, the skilled artisan simply needs to understand how to make and use fragments of SEQ ID NO 107 and how to make and use sequences having some defined degree of structural identity to SEQ ID NO 107, which subject matter is fully enabled by applicants disclosure. This

argument as well as pages 34-37 of the specification have been thoroughly reviewed but were not found persuasive. The specification, at pages 34-37 how to determine degrees of % identity between nucleic acids (p 34-36), teaches that fragments of SEQ ID NO 107 could have certain lengths (last para p. 36), and contemplates combining polynucleotides of the invention with promoters, for example, that could vary the overall length of the polynucleotides (p. 37). The specification, however, does not establish a predictable correlation as to which changes could be made to SEQ ID NO 107 to yield mutants, variants, and homologs of SEQ ID NO 107, with either retained or altered biological activity of the resulting encoded protein. The *full scope* of the claims encompass such changes, however the specification has not provided enough guidance such that the skilled artisan could determine which changes could be made to result in a protein with either altered or retained biological function. Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art".

The response traverses that the current claims are drawn to isolated polynucleotides, not isolated polypeptides, and that it is the prostate tumor associated expression profile identified by applicants for SEQ ID NO 107, and not the biological function of the encoded polypeptide of SEQ ID NO 108 that is most pertinent to enablement of the presently claimed invention. The

response traverses that the biological function of SEQ ID NO 108 is irrelevant to the overexpression of SEQ ID NO 107 in prostate cancer tissues and that in view of the disclosure in the specification, the individual skilled in the diagnostic arts would immediately appreciate that SEQ ID NO 107, or the genus of polynucleotides encompassed by fragments and % identity language could be used as a probe, though hybridization techniques, to detect over expression of mRNA corresponding to SEQ ID NO 107 relative to a suitable negative control to determine if a tissue sample is indicative of cancerous prostate tissue. This argument has been thoroughly reviewed but was found unpersuasive. Firstly, the claims are drawn to products, and not to methods, such that the intended use of the polynucleotide does not encompass the full scope of the claimed polynucleotides. While SEQ ID NO 107 can be used as a probe to detect overexpression of SEQ ID NO 107, and the specification enables such, the claimed nucleic acids are also drawn to mutants, variants, homologs, and fragments of SEQ ID NO 107 containing intronic and non coding sequences that have not been taught by the specification. Further, the specification does not teach what changes to SEQ ID NO 107 can be made to yield mutants, variants, and homologs of SEQ ID NO 107 with retained or altered biological activities. As such are encompassed by the full scope of the claimed invention, the specification fails to enable the broad scope of the claims. As stated previously, Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope

of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". While some of the claimed genus of variants of SEQ ID NO 108, that is sequences related by structural identity to SEQ ID NO 107, could be used to detect expression of SEQ ID NO 107, such sequences encompass nucleic acids encoding proteins that have not been taught or contemplated in the specification. These sequences are encompassed by the *full scope* of the claims, but are not taught by the specification. For example, a sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal α-methylacyl-CoA racemace which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while the specification, does not teach or suggest the use of the claimed polypeptides with adult onset sensory motor neuropathy, does not teach the function or biological activity of the polypeptide of SEQ ID NO 108 and specifically teaches that no significant homologies were found with SEQ ID NO 107 and the EMBL and GenBank databases (p. 120, lines 15-16). For these reasons and the reasons made of record above, the rejection is maintained.

Written Description

6. Claims 65-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to 1) polynucleotides comprising fragments comprising at least 75 or 150 consecutive nucleotides of SEQ ID NO 107 (claims 65-66), 2) polynucleotides comprising a sequence having at least 75%, 85% or 95% sequence identity to the entirety of SEQ ID NO 107 (claims 67-69), 3) polynucleotides having at least 90% or 95% identity to a sequence comprising at least 150 consecutive nucleotides of SEQ ID NO 107 (claims 70-71), and 4) complete complements of such sequences (claim 72). The full genus of the claimed polynucleotides encompass mutants, variants and homologs of the polynucleotide of SEQ ID NO 107 as well as fragments which include non coding sequences of the polynucleotide of SEQ ID NO 107, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 is a full length cDNA which was found to be over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 131, line 16-page 132 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out of 5 prostate carcinoma samples tested. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer.

The claims, however, encompass mutants, variants, and homologs of SEQ ID NO 107, but the specification has not taught any mutants, variants, or homologs of SEQ ID NO 107 that are overexpressed in prostate cancer such that a predictable correlation could be made that mutants, variants, or homologs of SEQ ID NO 107 are overexpressed in prostate tumor tissue. Further, the specification, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that polynucleotides of the invention may comprise a native sequence (sentence bridging pages 33 and 34) or may comprise a variant, or a biological or antigenic functional equivalent of such. The specification, however, does not teach or describe any variants with mutant or retained biological activity of the polypeptide of SEQ ID NO 108, nor does the specification teach or describe what regions of SEQ ID NO 108 are antigenic, or immunogenic, or responsible for it's biological activity. Although the specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), the specification does not teach the function of any of these splice variants or whether they were over expressed in prostate tumor samples vs normal prostate tissue.

Polynucleotides encompassed by the claims however, include a large number of mutants, variants, and homologs of SEQ ID NOS 107 resulting from missense, frameshift and truncation mutations, from any source, which have not been taught in either the specification or the art. Polynucleotide sequences comprising a fragment comprising at least 75 or 150 consecutive nucleotides of SEQ ID NO 107 or complete complements of such, encompasses fragments that include genomic sequences such as intronic or non coding sequences of SEQ ID NO 107, that

have not been taught or described in the specification, as well as homologs, mutants, or variants of SEQ ID NO 107 that have only 75 or 150 nucleotides in common with SEQ ID NO 107. Polynucleotides comprising a sequence having at least 75%, 85%, or 95% to the entirety of SEQ ID NO 107, complete complements of such, polynucleotides having at least 90% or 95% to a sequence comprising at least 150 consecutive nucleotides of SEQ ID NO 107 or complete complements of such also encompass mutants, variants, and homologs of SEQ ID 107, from any source, with either retained or altered biological activity, that have not been taught in the specification. The specification does not teach the function or biological activity of the polypeptide of SEQ ID NO 108, nor an assay to measure such, so that the skilled artisan would not know which modifications to the polypeptide of SEQ ID NO 108 would result in a polypeptide with altered biological activity. Further, the specification does not indicate which amino acids of SEQ ID NO 108 are responsible for it's activity such that the skilled artisan might be able to establish a predictable correlation between which amino acids could be altered to provide a polypeptide with either retained or altered biological activity to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity. Therefore, the skilled artisan would first be required to determine the biological activity of the polypeptide encoded by SEQ ID NO 107. Secondly, the skilled artisan would have to determine which amino acids were involved in such function, using trial and error analysis. Such analysis could involve mutating amino acids individually, to determine whether conservative or nonconservative mutations would affect the function of the resulting polypeptide.

Given the lack of guidance in the specification as to the function of SEQ ID NO 108, such analysis would be unpredictable, and therefore, constitutes undue experimentation.

A sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal α-methylacyl-CoA racemace which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). The genus of polynucleotides encompassed by each of the rejected claims include the polynucleotide encoding the polypeptide [both] taught by Ferdinandeuse. Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while the specification, does not teach or suggest the polynucleotide or polypeptide taught by Ferdinandeuse, the use of the claimed polypeptides with adult onset sensory motor neuropathy, does not teach the function or biological activity of the polypeptide of SEQ ID NO 108 and specifically teaches that no significant homologies were found with SEQ ID NO 107 and the EMBL and GenBank databases (p. 120, lines 15-16).

Since the specification does not teach or describe the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the disclosed structural feature of the polypeptide of SEQ ID NO 108 and the polynucleotide of SEQ ID NO 107 does represent a substantial portion of the claimed genus of polynucleotides.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a polynucleotide comprising SEQ ID NO 107 and the complete complement of such, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claims 65-72.

Response to Arguments

The response traverses the rejection. The response traverses that the specification more than adequately describes relevant and distinguishing identifying characteristics sufficient to establish that Applicants were in possession of the genus of polynucleotides currently claimed at the time the application was filed. The response asserts that an illustrative sufficient and relevant identifying characteristics shared by members of the currently claimed genus is their ability to be used in the detection of prostate cancer. The response further asserts that the biological function of the polypeptide of SEQ ID NO 108 is not relevant to the over expression of SEQ ID NO 107 in cancer tissue relative to normal tissue. The response asserts that in view of the general knowledge in the art, the skilled artisan would understand and expect that a genus of polypeptides structurally related to SEQ ID NO 107 could be used in the context of applicants's invention, the detection of prostate cancer. These argument have been thoroughly reviewed but were not found persuasive. As stated previously, the full genus of claims are drawn to mutants, variants, homologs, and sequences comprising genomic DNA of SEQ ID NO 107, that have not been taught in the specification. The intended use of the claimed polynucleotides does not exclude the broad genus of claimed polynucleotides, for which the specification does not teach a representative number of species of the claimed genus. The specification teaches the single nucleic acid of SEQ ID NO 107. The specification does not teach any mutants, variants or

homologs of SEQ ID NO 107 that are overexpressed in prostate cancer. The specification does not teach any intronic sequences of SEQ ID NO 107 that are encompassed by the claims. The specification does not teach or suggest the function of the polypeptides that could be encoded by the claimed polynucleotides. The art supports that substantial variations are encompassed by the genus of claimed nucleic acids, for which the specification has provided no guidance. For example, a sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal α-methylacyl-CoA racemace which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). The genus of polynucleotides encompassed by each of the rejected claims include the polynucleotide encoding the polypeptide [both] taught by Ferdinandeuse. Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while *the specification, does not teach or suggest* (emphasis added) the polynucleotide or polypeptide taught by Ferdinandeuse, or the use of the claimed polypeptides with adult onset sensory motor neuropathy. Further, the specification has not taught what structural attributes or features are common between the polynucleotide of Ferdinandeuse and SEQ ID NO 107. For these reasons and the reasons made of record above, the rejection is maintained.

Indefinite

7. Claims 65 -67 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 65 and 66 are indefinite as it cannot be determined if the claims encompass a fragment of SEQ ID NO 107 which comprises at least 75 or 150 consecutive nucleotide residues of SEQ ID NO 107, or to a polynucleotide *comprising* a fragment of SEQ ID NO 107 which comprises 75 or 150 consecutive nucleotide residues of SEQ ID NO 107. Neither the specification nor the claims make clear whether the fragment is itself within a larger sequence, and thus the metes and bounds of the claims are unclear.

Claim 67 is indefinite as the preamble of the claim indicates that the claim is drawn to a polynucleotide, however the claim recites SEQ ID NO 108, which is a polypeptide. See section 2 above.

Double Patenting

8. Claims 64-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of U.S. Patent No. 6,262,245. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the '245 patent is drawn to an isolated DNA molecule comprising the sequence of SEQ ID NO 107 and claim 10 is drawn to polynucleotides that encode the polypeptide encoded by SEQ ID NO 107. Claims 64-66 are drawn to polynucleotides

comprising SEQ ID NO 107 and polynucleotides comprising fragments of SEQ 107. Since the specification does not define a length limitation for the terms "polynucleotide" the claims are coextensive in scope and claims 64-66 are encompassed by the recitation of claim 1 of the '245 patent. Further, claim 10 of the '245 patent is drawn to polynucleotides that encode the polypeptide encoded by SEQ ID NO 107, which encompass degenerate variants of the polynucleotide of SEQ ID NO 107, which are coextensive in scope with claims 67-71 of the present application, which are drawn polynucleotides that have a certain % identity to SEQ ID NO 107.

Response to Arguments

The response indicates that a terminal disclaimer will be filed in due course in view of subject matter deemed allowable by the examiner.

9. Claims 64-72 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 3-4 of copending Application Nos. 09/895,814, 09/780,669, and 09/759,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1, section a of the '814, '669, and '143 applications recites in the alternative "an isolated polynucleotide comprising a sequence provided in SEQ 107", section b recites "complements of the sequence provided in SEQ ID NO 107", and section d recites "sequences that hybridize to a sequence provided in SEQ ID NO 107". It is noted that SEQ ID NO 107 in the instant application is identical to SEQ ID

NO 107 from the '814, '669, and '143 applications. Claims 64-71 of the instant application are drawn to polynucleotides, fragments, and variants of SEQ ID NO 107. Since the specification does not define a length limitation for the term polynucleotide the claims are coextensive in scope and the instantly pending claims are encompassed by the recitation of claim 1, section a of the '814, '669, and '143 applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 64-72 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-10, 16, and 58-60 of copending Application Nos. 09/636,215, 09/593,793, 09/605,783, and 09/568,100. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 64-72 of the instant application are drawn to polynucleotides, fragments, variants, and full complements of SEQ ID NO 107. Claims 4-10, 16, and 58-60 from the '215, '793, '783, and '100 applications are also drawn, in the alternative, to polynucleotides and oligonucleotides of SEQ ID NO 107. SEQ ID NO 107 of the instant application, and SEQ ID NO 107 from the '215, '793, '783, and '100 applications are identical, and therefore, the claims are coextensive in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The response does not traverse the rejections in sections 8 and 9 above. Accordingly, the rejections are made final.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowable. Claim 64 would be allowable upon the submission of a terminal disclaimer.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
12/12/02